



AF/3739

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Victor I. Chornenky et al.      Group Art Unit:      3739  
Serial No.:      09/783,577      Examiner:      D. Shay  
Filed:      February 12, 2001      Attorney Docket No.: 009.1009C  
For:      X-RAY CATHETER

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APPEAL BRIEF OF THE APPELLANT PURSUANT TO 37 C.F.R. § 1.192

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by   
David K. Benson Reg. No. 42,314

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## **I. INTRODUCTION**

This is an Appeal Brief of the Appellant pursuant to 37 C.F.R. § 1.192 appealing the final rejection of the Examiner mailed April 29, 2002. The Appeal Brief of the Appellant is provided herein in triplicate, and each of the topics required by 37 C.F.R. § 1.192 is presented in this Appeal Brief and is labeled appropriately.

## **II. REAL PARTY IN INTEREST**

Medtronic AVE, Inc. ("Medtronic") is the real party in interest of the present application. An assignment of all rights in the present application to Medtronic was executed by the inventors and recorded by the U.S. Patent and Trademark Office at Reel 010745, Frame 0231.

## **III. RELATED APPEALS AND INTERFERENCES**

There are no appeals or interferences related to the present application of which Appellant is aware.

## **IV. STATUS OF CLAIMS**

Claims 24 to 37, which are presented in the Appendix, are the only claims pending in the present application. However, the Examiner indicates in the final office action that these claims are withdrawn from consideration.

The application as filed included claims 1 to 45 in the specification. A preliminary amendment filed on the application's filing date canceled claims 1 to 23, and 38 to 45. However, the Examiner indicates in the final office action that these canceled claims are rejected.

## **V. STATUS OF AMENDMENTS**

There are no outstanding amendments to the claims that have been filed subsequent to the final rejection of the claims in the final office action.

## **VI. SUMMARY OF THE INVENTION**

The present invention relates generally to methods of using an x-ray catheter that is sufficiently small and flexible to access an intended site within a vascular system of the body, such as the coronary arteries of the cardiovascular system. More particularly, the present invention is directed to methods of performing an x-ray treatment (claim 37) such as a treatment to prevent restenosis of a lumen (claims 24 to 36).

A first method according to the present invention is directed to performing an x-ray treatment (claim 37). The method includes the first step of advancing an x-ray catheter (i.e., catheter 10 in FIG. 1) through a lumen (i.e., vessel or lumen 410 in FIG. 9) to a first location adjacent an intended site (page 5, lines 18 to 22; page 7, lines 1 to 5; page 20, lines 20 to 22; page 31, lines 23 to 26). The x-ray catheter comprises a flexible catheter shaft (12) with an x-ray generating unit coupled to the shaft's distal end (page 9, lines 12 to 13). The x-ray generating unit comprises an anode (20), a cathode (18) and an insulator (page 10, lines 17 to 25) that defines a vacuum chamber (16). The method also includes the step of causing the emission of an effective dose of x-ray radiation (page 14, line 4 to page 15, line 20). After the x-ray radiation is emitted, the x-ray unit is either positioned at one or more additional positions for emission of additional radiation (claims 34 and 35) until ultimately the emission processes are completed and the catheter is removed.

A second method according to the present invention is directed to preventing restenosis of a lumen (claims 24 to 36), and in one embodiment (claim 36) following an angioplasty procedure (page 33, lines 10 to 22). In the broadest sense, as recited in claim 24, the method includes the same steps as those previously described steps pertaining to

the first method, although the method in the second method specifies that the dose of x-ray radiation is effective to prevent restenosis (page 22, line 4 to page 23, line 4). As recited in claim 25, the radiation can be emitted within a particular energy range to achieve a particular depth of penetration (page 22, lines 12 to 16). To achieve the particular depth penetration, a predetermined voltage can be applied between the anode and the cathode (page 22, lines 8 to 11). In one embodiment (claim 29), x-rays are emitted having an energy of about 8 - 10 KeV (page 23, lines 20 to 24).

As recited in claims 27 to 28, the method can further include the step of irradiating tissue. In one embodiment (claim 27), the tissue is irradiated a rate of about 1 - 50 grays per minute (page 23, lines 17 to 26). In another embodiment (claim 28), that irradiation rate is conducted for about one minute (page 23, lines 20 to 24).

The method can further include the step of centering the x-ray unit within the lumen prior to causing radiation to be emitted (claim 30; page 28, line 24 to page 31, line 16). Centering the x-ray unit within the lumen to enable a uniform distribution of radiation during the irradiating step and after the x-ray catheter is advanced to the intended treatment site. Advancing the catheter through a lumen of the vascular system may be performed through an exchange tube (claim 31; page 31, lines 19 to 26). In another embodiment, at least a portion of catheter is advanced through a lumen of the vascular system over a guide wire and through a guide catheter (claims 32 to 33; page 32, lines 1 to 19).

## **VII. ISSUES**

The issues present in this appeal before the U.S. Board of Patent Appeals and Interferences are as follows:

- A. Are claims 1 to 5, 10 to 16, 18 to 21, 38, and 43 anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,090,043 (hereinafter Parker)?
- B. Are claims 6 to 9, 17, 22 to 23, 39 to 42, and 44 to 45 unpatentable under 35 U.S.C. § 103(a) over Parker?

## **VIII. GROUPING OF CLAIMS**

For purposes of the issues presented by this appeal before the U.S. Board of Appeals and Interferences, the claims 1 to 23, and 38 to 45 stand or fall together. In addition, claims 24 to 37 stand or fall together for purposes of the issues presented by this appeal.

## **IX. ARGUMENTS**

### **THE REJECTIONS OF CLAIMS 1 TO 23, AND 38 TO 45 UNDER 35 U.S.C. §§ 102, 103 SHOULD NOT BE SUSTAINED BECAUSE SUCH CLAIMS ARE CANCELED.**

A preliminary amendment filed on the application's filing date canceled claims 1 to 23, and 38 to 45. Consequently, only claims 24 to 37 are pending for examination, and the rejections of claims 1 to 23, and 38 to 45 are moot and should not be sustained.

It is of course understood that this appeal of an erroneous final rejection of canceled claims may appear to result in part from a lack of communication between the Appellant and the examiner. Indeed, a communication failure between the two is primarily the basis for this appeal.

The present application is a continuation of parent application 08/701,764 in which claims 1 to 23, and 38 to 45 were elected for examination. After receiving a notice of allowance in the parent application, Appellant filed the present application, along with the preliminary amendment canceling claims 1 to 23, and 38 to 45 in favor of claims 24 to 37. The examiner seemingly did not notice the preliminary amendment and consequently examined the claims elected in the parent application by default. The examiner did not find any submitted arguments or amendments associated with claims 1 to 23, and 38 to 45, so the examiner issued a first and final action on the merits.

Shortly after receiving the final action, Appellant contacted the examiner by telephone and requested that a new and non-final office action be mailed, including an examination of claims 24 to 37, the only claims pending in the application. The attached docket sheet dated September 3, 2002 includes a record of the telephone conversation, recorded to have taken place on June 27, 2002. As indicated on the sheet, during at least this telephone call to the examiner the Appellant was assured by the examiner that the final office action was retracted, and that a new and non-final office action would be shortly mailed. However, the examiner failed to ever issue another action, and Appellant inadvertently allowed the present application to become abandoned while awaiting issuance of another action. A notice of appeal accompanied a petition to revive the unintentionally abandoned application filed under 37 C.F.R. § 1.137(b), and this brief followed a decision granting the petition. Appellant regrets that a cooperative agreement could not be made with the examiner before this appeal. This action by Appellant is an attempt to forward the present application through the examination process, including an examination of pending claims 24 to 37, following fruitless efforts to do so through direct correspondence with the examiner.

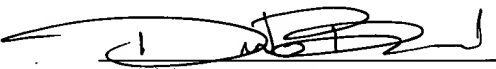
For the above reasons it is respectfully submitted that the rejections of canceled claims 1 to 23, and 38 to 45 should not be sustained. In addition, it is respectfully requested that the case be remanded to the examiner for an examination of pending claims 24 to 37.

**X. CONCLUSION**

In view of the foregoing, Appellant respectfully submits that the final rejection of Claims 1 to 23, and 38 to 45 is improper and the U.S. Board of Patent Appeals and Interferences is respectfully requested to reverse the Examiner's rejections and remand the case for an examination of claims 24 to 37.

Respectfully submitted,

Dated 27 Aug 2004

  
David K. Benson  
Registration No. 42,314

Ingrassia Fisher & Lorenz, PC  
Customer No. 29,906

7150 E. Camelback Rd., Suite 325  
Scottsdale, Arizona 85251  
Telephone: (480) 385-5060  
Facsimile: (480) 385-5061



## **XI. APPENDIX - CLAIMS ON APPEAL**

24. A method for preventing restenosis of a lumen comprising:

(a) advancing an x-ray catheter through a lumen to a first location adjacent an intended site of the lumen, wherein the x-ray catheter comprises a flexible catheter shaft with a distal end and an x-ray generating unit coupled to the distal end, the x-ray generating unit comprising an anode, a cathode and an insulator, wherein the anode and cathode are coupled to the insulator to define a vacuum chamber;

(b) causing the emission of an effective dose of x-ray radiation to prevent restenosis; and

(c) removing the catheter.

25. The method of claim 24, wherein step (b) comprises causing the emission of radiation within a particular energy range to achieve a particular depth of penetration.

26. The method of claim 24, wherein the causing step (b) further comprises applying a predetermined voltage between the anode and the cathode to achieve the particular depth penetration.

27. The method of claim 24, further comprising irradiating tissue at a rate of about 1 - 50 grays per minute.

28. The method of claim 27, wherein the irradiating step is conducted for about 1 minute.

29. The method of claim 24, wherein step (b) comprises causing the emission of x-rays having an energy of about 8 - 10 KeV.

30. The method of claim 24, further comprising centering the x-ray unit within the lumen prior to the step (b).

31. The method of claim 24, wherein the advancing step comprises advancing the x-ray catheter through a lumen of the vascular system through an exchange tube.

32. The method of claim 24, wherein the advancing step comprises advancing the x-ray catheter through a lumen of the vascular system over a guide wire and through a guide catheter.

33. The method of claim 32, wherein a portion of the x-ray catheter is advanced over the guide wire.

34. The method of claim 24, further comprising positioning the x-ray unit at a second location and causing the emission of x-ray radiation at the second location.

35. The method of claim 24, further comprising positioning the x-ray unit at a plurality of locations and causing the emission of x-ray radiation at each of the plurality of locations.

36. The method of claim 24, further comprising conducting an angioplasty procedure prior to step (a), wherein the intended site of step (a) is the site of the angioplasty procedure.

37. A method for providing x-ray radiation treatment, comprising:

advancing an x-ray catheter through a lumen to a first location adjacent an intended site, wherein the x-ray catheter comprises a flexible catheter shaft with a distal end and an x-ray generating unit coupled to the distal end, the x-ray generating unit comprising an anode, a cathode and an insulator to define a vacuum chamber;

causing the emission of an effective dose of x-ray radiation; and

removing the catheter.

09/03/2002

## Patent Information Print

Docket No	PA775	Grant Dt	
Country	United States	Publication #	20010009970
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Relation Type	Continuation	Assigned	
Filing Type	National Case	Expiration Dt	
Filing No	02	Conv Type	
Attorney	Catherine C. Maresh	Tax Base Dt	
Client\Divisio	AVE	Group	Vascular
Current Owner	Medtronic AVE Inc.	Next Tax Dt	
Prev Own	XRT Corporation	Agent	
File Location		Associate	
Status	Filed	Secretary	
First Filing D	08/24/1995	Assignee	Medtronic AVE Inc.
Sub Stat	Pending	Sub Division	AVE XRT
Sub Stat Dt	04/04/2001	Medt Atty 2	
Parent Country	United States	Ag Ref No	
Parent Filing	08/24/1995	Verified	N
Parent No	60/002722	Customer	MDPP
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Total Claims		Update Dt	07/17/2002
Ind. Claims		Update Tm	1833
Application #	09/783577	Update User	GLBC
Application Dt	02/12/2001	Update Type	A
Patent No			

## \*\*Actions\*\*

Action	Formal Drawings	DeadLn Dt	
Act Due Date	02/12/2001	Comp Dt	02/12/2001
Taken Dt	02/12/2001	Resp Atty #1	Christine L. Aceves

Act Notes  
Review file and drawings.

Action	Notice of Missing Parts*	DeadLn Dt	
Act Due Date	04/12/2001	Comp Dt	04/12/2001
Taken Dt		Resp Atty #1	Catherine C. Maresh

Action	Info Disc Stmt-3mo*	DeadLn Dt	
Act Due Date	05/12/2001	Comp Dt	10/19/2001
Taken Dt		Resp Atty #1	Catherine C. Maresh

Act Notes  
19-Oct-01 per CCM no other prior art to be cited.

Action	Filing Receipt	DeadLn Dt	
Act Due Date	05/12/2001	Comp Dt	04/24/2001
Taken Dt		Resp Atty #1	

Action	To be Published w/Dwgs*	DeadLn Dt	
Act Due Date	06/12/2001	Comp Dt	07/26/2001
Taken Dt	07/26/2001	Resp Atty #1	

Action	Yearly File Review	DeadLn Dt	
Act Due Date	02/12/2003	Comp Dt	
Taken Dt		Resp Atty #1	Catherine C. Maresh

Act Notes  
27-Jun-02 after telephone conversatin with the Examiner the  
FOA received in April is retracted. New  
Office Action to be submitted.

Action	Status-Office Action	DeadLn Dt	
Act Due Date	02/12/2003	Comp Dt	05/07/2002
Taken Dt		Resp Atty #1	Catherine C. Maresh

## \*\*Inventors\*\*

Inventor	Chornenky Victor
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Inventor	Forman Michael R
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## \*\*Other Info\*\*

Other Info Cd	Case Number	Other Info Dt
Other Info	PA775 CON 2	

## \*\*Title\*\*

CHRISTINE,

WAITING FOR NEW  
OA. PERHAPS ~~WE~~ WE SHOULD  
CONTACT THE PTO?  
TR5 Kim